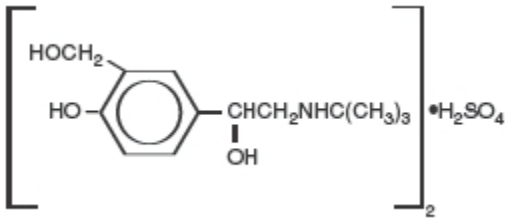
ALBUTEROL SULFATE - albuterol sulfate solution
Bausch & Lomb Incorporated

DESCRIPTION

Albuterol Sulfate Inhalation Solution, 0.5% contains albuterol sulfate, USP, the racemic form of albuterol and a relatively selective beta$_2$-adrenergic bronchodilator (see CLINICAL PHARMACOLOGY section below). Albuterol sulfate has the chemical name α^1-[(*tert*—Butylamino)methyl]-4-hydroxy-*m*-xylene-α, α'-diol sulfate (2:1) (salt), and the following structural formula:



$(C_{13}H_{21}NO_3)_2 \cdot H_2SO_4$
Mol. Wt. 576.71
Albuterol sulfate is a white crystalline powder, soluble in water and slightly soluble in ethanol.
The World Health Organization's recommended name for albuterol base is salbutamol.
Albuterol sulfate inhalation solution, 0.5% is in concentrated form. Dilute the appropriate volume of the solution (see DOSAGE AND ADMINISTRATION) with sterile normal saline solution to a total volume of 3 mL and administer by nebulization.
Each mL Contains: ACTIVE: Albuterol sulfate equivalent to 5 mg of albuterol in an aqueous solution. Sulfuric Acid may be added to adjust pH (3.0-5.0).
PRESERVATIVE ADDED: Benzalkonium Chloride 0.01%. Albuterol sulfate inhalation solution contains no sulfiting agents.
Albuterol sulfate inhalation solution is a clear, colorless to light yellow solution.

CLINICAL PHARMACOLOGY

In vitro studies and *in vivo* pharmacologic studies have demonstrated that albuterol has a preferential effect on beta$_2$-adrenergic receptors compared with isoproterenol. While it is recognized that beta$_2$-adrenergic receptors are the predominant receptors in bronchial smooth muscle, data indicate that there is a population of beta$_2$-receptors in the human heart existing in a concentration between 10% and 50%. The precise function of these receptors has not been established (see WARNINGS).
The pharmacologic effects of beta-adrenergic agonist drugs, including albuterol, are at least in part attributable to stimulation through beta-adrenergic receptors of intracellular adenyl cyclase, the enzyme that catalyzes the conversion of adenosine triphosphate (ATP) to cyclic-3',5'-adenosine monophosphate (cyclic AMP). Increased cyclic AMP levels are associated with relaxation of bronchial smooth muscle and inhibition of release of mediators of immediate hypersensitivity from cells, especially from mast cells.
Albuterol has been shown in most controlled clinical trials to have more effect on the respiratory tract, in the form of bronchial smooth muscle relaxation, than isoproterenol at comparable doses while producing fewer cardiovascular effects.
Controlled clinical studies and other clinical experience have shown that inhaled albuterol, like other beta-adrenergic agonist drugs, can produce a significant cardiovascular effect in some patients, as measured by pulse rate, blood pressure, symptoms, and/or electrocardiographic changes.
Albuterol is longer acting than isoproterenol in most patients by any route of administration because it is not a substrate for the cellular uptake processes for catecholamines nor for catechol-*O*-methyl transferase.
Pharmacokinetics: Studies in asthmatic patients have shown that less than 20% of a single albuterol dose was absorbed following either intermittent positive-pressure breathing (IPPB) or nebulizer administration; the remaining amount was recovered from the nebulizer and apparatus and expired air. Most of the absorbed dose was recovered in the urine within 24 hours after drug administration. Following a 3-mg dose of nebulized albuterol in adults, the maximum albuterol plasma levels at 0.5 hours were 2.1 ng/mL (range, 1.4 to 3.2 ng/mL). There was a significant dose-related response in FEV_1 (forced expiratory volume in 1 second) and peak flow rate. It has been demonstrated that following oral administration of 4 mg of albuterol, the elimination half-life was 5 to 6 hours.
Preclinical: Intravenous studies in rats with albuterol sulfate have demonstrated that albuterol crosses the blood-brain barrier and reaches brain concentrations amounting to approximately 5.0% of the plasma concentrations. In structures outside the brain barrier (pineal and pituitary glands), albuterol concentrations were found to be 100 times those in the whole brain.
Studies in laboratory animals (minipigs, rodents, and dogs) have demonstrated the occurrence of cardiac arrhythmias and sudden death (with histologic evidence of myocardial necrosis) when beta-agonists and methylxanthines are administered concurrently. The clinical significance of these findings is unknown.
Clinical Trials: In controlled clinical trials in adults, most patients exhibited an onset of improvement in pulmonary function within 5 minutes as determined by FEV_1. FEV_1 measurements also showed that the maximum average improvement in pulmonary function usually occurred at approximately 1 hour following inhalation of 2.5 mg of albuterol by compressor-nebulizer and remained close

to peak for 2 hours. Clinically significant improvement in pulmonary function (defined as maintenance of a 15% or more increase in FEV_1 over baseline values) continued for 3 to 4 hours in most patients, with some patients continuing up to 6 hours.
Published reports of trials in asthmatic children aged 3 years or older have demonstrated significant improvement in either FEV_1 or PEFR within 2 to 20 minutes following single doses of albuterol inhalation solution. An increase of 15% or more in baseline FEV_1 has been observed in children aged 5 to 11 years up to 6 hours after treatment with doses of 0.10 mg/kg or higher of albuterol inhalation solution. Single doses of 3, 4, or 10 mg resulted in improvement in baseline PEFR that was comparable in extent and duration to a 2-mg dose, but doses above 3 mg were associated with heart rate increases of more than 10%.

INDICATIONS AND USAGE
Albuterol sulfate inhalation solution is indicated for the relief of bronchospasm in patients 2 years of age and older with reversible obstructive airway disease and acute attacks of bronchospasm.

CONTRAINDICATIONS
Albuterol sulfate inhalation solution is contraindicated in patients with a history of hypersensitivity to albuterol or any of its components.

WARNINGS
Paradoxical Bronchospasm: Albuterol sulfate inhalation solution can produce paradoxical bronchospasm, which may be life threatening. If paradoxical bronchospasm occurs, albuterol sulfate inhalation solution should be discontinued immediately and alternative therapy instituted. It should be recognized that paradoxical bronchospasm, when associated with inhaled formulations, frequently occurs with the first use of a new canister or vial.
Fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs and with the home use of nebulizers. It is therefore essential that the physician instruct the patient in the need for further evaluation if his/her asthma becomes worse.
Cardiovascular Effects: Albuterol sulfate inhalation solution, like all other beta-adrenergic agonists, can produce a clinically significant cardiovascular effect in some patients as measured by pulse rate, blood pressure, and/or symptoms. Although such effects are uncommon after administration of albuterol sulfate inhalation solution at recommended doses, if they occur, the drug may need to be discontinued. In addition, beta-agonists have been reported to produce electrocardiogram (ECG) changes, such as flattening of the T wave, prolongation of the QTC interval, and ST segment depression. The clinical significance of these findings is unknown. Therefore, albuterol sulfate inhalation solution, like all sympathomimetic amines, should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.
Deterioration of Asthma: Asthma may deteriorate acutely over a period of hours or chronically over several days or longer. If the patient needs more doses of albuterol sulfate inhalation solution than usual, this may be a marker of destabilization of asthma and requires reevaluation of the patient and treatment regimen, giving special consideration to the possible need for anti-inflammatory treatment, e.g., corticosteroids.
Immediate Hypersensitivity Reactions: Immediate hypersensitivity reactions may occur after administration of albuterol, as demonstrated by rare cases of urticaria, angioedema, rash, bronchospasm, and oropharyngeal edema.
Use of Anti-inflammatory Agents: The use of beta-adrenergic agonist bronchodilators alone may not be adequate to control asthma in many patients. Early consideration should be given to adding anti-inflammatory agents, eg, corticosteroids.
Microbial Contamination: To avoid microbial contamination, proper aseptic technique should be used each time the bottle is opened. Precautions should be taken to prevent contact of the dropper tip of the bottle with any surface, including the nebulizer reservoir and associated ventilatory equipment. In addition, if the solution changes color or becomes cloudy, it should not be used.

PRECAUTIONS

General
Albuterol, as with all sympathomimetic amines, should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, hypertension, and cardiac arrhythmia; in patients with convulsive disorders, hyperthyroidism, or diabetes mellitus; and in patients who are unusually responsive to sympathomimetic amines.
Clinically significant changes in systolic and diastolic blood pressure have been seen in individual patients and could be expected to occur in some patients after use of any betaadrenergic bronchodilator.
Large doses of intravenous albuterol have been reported to aggravate preexisting diabetes mellitus and ketoacidosis. As with other beta-agonists, albuterol may produce significant hypokalemia in some patients, possibly through intracellular shunting, which has the potential to produce adverse cardiovascular effects. The decrease is usually transient, not requiring supplementation.
Repeated dosing with 0.15 mg/kg of albuterol inhalation solution in children aged 5 to 17 years who were initially normokalemic has been associated with an asymptomatic decline of 20% to 25% in serum potassium levels.

Information for patients
The action of albuterol sulfate inhalation solution may last up to 6 hours or longer. Albuterol sulfate inhalation solution should not be used more frequently than recommended. Do not increase the dose or frequency of albuterol sulfate inhalation solution without

consulting your physician. If you find that treatment with albuterol sulfate inhalation solution becomes less effective for symptomatic relief, your symptoms become worse, and/or you need to use the product more frequently than usual, you should seek medical attention immediately. While you are using albuterol sulfate inhalation solution, other inhaled drugs and asthma medications should be taken only as directed by your physician. Common adverse effects include palpitations, chest pain, rapid heart rate, and tremor or nervousness. If you are pregnant or nursing, contact your physician about use of albuterol sulfate inhalation solution. Effective and safe use of albuterol sulfate inhalation solution includes an understanding of the way that it should be administered.
To avoid microbial contamination, proper aseptic techniques should be used each time the bottle is opened. Precautions should be taken to prevent contact of the dropper tip of the bottle with any surface, including the nebulizer reservoir and associated ventilatory equipment. In addition, if the solution changes color or becomes cloudy, it should not be used.
Drug compatibility (physical and chemical), efficacy, and safety of albuterol sulfate inhalation solution when mixed with other drugs in a nebulizer have not been established.
See illustrated Patient's Instructions for Use.

Drug interactions
Other short-acting sympathomimetic aerosol bronchodilators or epinephrine should not be used concomitantly with albuterol. If additional adrenergic drugs are to be administered by any route, they should be used with caution to avoid deleterious cardiovascular effects.
Monoamine Oxidase Inhibitors or Tricyclic Antidepressants: Albuterol should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors or tricyclic antidepressants, or within 2 weeks of discontinuation of such agents, because the action of albuterol on the vascular system may be potentiated.
Beta-Blockers: Beta-adrenergic receptor blocking agents not only block the pulmonary effect of beta-agonists, such as albuterol sulfate inhalation solution, but may produce severe bronchospasm in asthmatic patients. Therefore, patients with asthma should not normally be treated with beta-blockers. However, under certain circumstances, e.g., as prophylaxis after myocardial infarction, there may be no acceptable alternatives to the use of beta-adrenergic blocking agents in patients with asthma. In this setting, cardioselective beta-blockers could be considered, although they should be administered with caution.
Diuretics: The ECG changes and/or hypokalemia that may result from the administration of nonpotassium-sparing diuretics (such as loop or thiazide diuretics) can be acutely worsened by beta-agonists, especially when the recommended dose of the beta-agonist is exceeded. Although the clinical significance of these effects is not known, caution is advised in the coadministration of beta-agonists with nonpotassium-sparing diuretics.
Digoxin: Mean decreases of 16% to 22% in serum digoxin levels were demonstrated after single-dose intravenous and oral administration of albuterol, respectively, to normal volunteers who had received digoxin for 10 days. The clinical significance of these findings for patients with obstructive airway disease who are receiving albuterol and digoxin on a chronic basis is unclear. Nevertheless, it would be prudent to carefully evaluate the serum digoxin levels in patients who are currently receiving digoxin and albuterol.

Carcinogenesis, mutagenesis, impairment of fertility
In a 2-year study in Sprague-Dawley rats, albuterol sulfate caused a significant dose-related increase in the incidence of benign leiomyomas of the mesovarium at dietary doses of 2.0, 10, and 50 mg/kg (approximately 2, 8, and 40 times, respectively, the maximum recommended daily inhalation dose for adults on a mg/m^2 basis or approximately 3/5, 3, and 15 times, respectively, the maximum recommended daily inhalation dose in children on a mg/m^2 basis). In another study this effect was blocked by the coadministration of propranolol, a nonselective beta-adrenergic antagonist. In an 18-month study in CD-1 mice, albuterol sulfate showed no evidence of tumorigenicity at dietary doses of up to 500 mg/kg (approximately 200 times the maximum recommended daily inhalation dose for adults on a mg/m^2 basis or approximately 75 times the maximum recommended daily inhalation dose for children on a mg/m^2 basis). In a 22-month study in the Golden hamster, albuterol sulfate showed no evidence of tumorigenicity at dietary doses of up to 50 mg/kg (approximately 25 times the maximum recommended daily inhalation dose for adults on a mg/m^2 basis or approximately 10 times the maximum recommended daily inhalation dose for children on a mg/m^2 basis).
Albuterol sulfate was not mutagenic in the Ames test with or without metabolic activation using tester strains *S. typhimurium* TA1537, TA1538, and TA98 or *E. coli* WP2, WP2uvrA, and WP67. No forward mutation was seen in yeast strain *S. cerevisiae* S9 nor any mitotic gene conversion in yeast strain *S. cerevisiae* JD1 with or without metabolic activation.
Fluctuation assays in *S. typhimurium* TA98 and *E. coli* WP2, both with metabolic activation, were negative. Albuterol sulfate was not clastogenic in a human peripheral lymphocyte assay or in an AH1 strain mouse micronucleus assay at intraperitoneal doses of up to 200 mg/kg.
Reproduction studies in rats demonstrated no evidence of impaired fertility at oral doses up to 50 mg/kg (approximately 40 times the maximum recommended daily inhalation dose for adults on a mg/m^2 basis).

Pregnancy
Pregnancy Category C. Albuterol has been shown to be teratogenic in mice. A study in CD-1 mice at subcutaneous (sc) doses of 0.025, 0.25, and 2.5 mg/kg (approximately 1/100, 1/10, and 1.0 times, respectively, the maximum recommended daily inhalation dose

for adults on a mg/m2 basis) showed cleft palate formation in 5 of 111 (4.5%) fetuses at 0.25 mg/kg and in 10 of 108 (9.3%) fetuses at 2.5 mg/kg. The drug did not induce cleft palate formation at the lowest dose, 0.025 mg/kg. Cleft palate also occurred in 22 of 72 (30.5%) fetuses from females treated with 2.5 mg/kg of isoproterenol (positive control) subcutaneously (approximately 1.0 times the maximum recommended daily inhalation dose for adults on a mg/m^2 basis).

A reproduction study in Stride Dutch rabbits revealed cranioschisis in 7 of 19 (37%) fetuses when albuterol was administered orally at a 50-mg/kg dose (approximately 80 times the maximum recommended daily inhalation dose for adults on a mg/m^2 basis).

There are no adequate and well-controlled studies in pregnant women. Albuterol should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

During worldwide marketing experience, various congenital anomalies, including cleft palate and limb defects, have been rarely reported in the offspring of patients being treated with albuterol. Some of the mothers were taking multiple medications during their pregnancies. No consistent pattern of defects can be discerned, and a relationship between albuterol use and congenital anomalies has not been established.

Labor and delivery

Because of the potential for beta-agonist interference with uterine contractility, use of albuterol sulfate inhalation solution for relief of bronchospasm during labor should be restricted to those patients in whom the benefits clearly outweigh the risk.

Tocolysis: Albuterol has not been approved for the management of preterm labor. The benefit:risk ratio when albuterol is administered for tocolysis has not been established.

Serious adverse reactions, including maternal pulmonary edema, have been reported during or following treatment of premature labor with $beta_2$-agonists, including albuterol.

Nursing mothers

It is not known whether this drug is excreted in human milk. Because of the potential for tumorigenicity shown for albuterol in some animal studies, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric use

The safety and effectiveness of albuterol sulfate inhalation solution have been established in children 2 years of age and older. Use of albuterol sulfate inhalation solution in these age-groups is supported by evidence from adequate and well-controlled studies of albuterol sulfate inhalation solution in adults; the likelihood that the disease course, pathophysiology, and the drug's effect in pediatric and adult patients are substantially similar; and published reports of trials in pediatric patients 3 years of age or older.

The recommended dose for the pediatric population is based upon three published dose comparison studies of efficacy and safety in children 5 to 17 years, and on the safety profile in both adults and pediatric patients at doses equal to or higher than the recommended doses. The safety and effectiveness of albuterol sulfate inhalation solution in children below 2 years of age have not been established.

ADVERSE REACTIONS

The results of clinical trials with albuterol sulfate inhalation solution in 135 patients showed the following side effects that were considered probably or possibly drug related:

Percent Incidence of Adverse Reactions

Reaction	Percent Incidence Reaction n=135
Central Nervous System	
Tremors	20%
Dizziness	7%
Nervousness	4%
Headache	3%
Sleeplessness	1%
Gastrointestinal	
Nausea	4%
Dyspepsia	1%
Ear, nose and throat	
Nasal congestion	1%
Pharyngitis	<1%
Cardiovascular	
Tachycardia	1%
Hypertension	1%

Respiratory	
Bronchospasm	8%
Cough	4%
Bronchitis	4%
Wheezing	1%

No clinically relevant laboratory abnormalities related to albuterol sulfate inhalation solution administration were determined in these studies.
Cases of urticaria, angioedema, rash, bronchospasm, hoarseness, oropharyngeal edema, and arrhythmias (including atrial fibrillation, supraventicular tachycardia, extrasystoles) have been reported after the use of albuterol sulfate inhalation solution.

OVERDOSAGE
The expected symptoms with overdosage are those of excessive betaadrenergic stimulation and/or occurrence or exaggeration of any of the symptoms listed under ADVERSE REACTIONS, e.g., seizures, angina, hypertension or hypotension, tachycardia with rates up to 200 beats/min, arrhythmias, nervousness, headache, tremor, dry mouth, palpitation, nausea, dizziness, fatigue, malaise, and sleeplessness. Hypokalemia may also occur. In isolated cases in children 2 to 12 years of age, tachycardia with rates >200 beats/min has been observed.
As with all sympathomimetic medications, cardiac arrest and even death may be associated with abuse of albuterol sulfate inhalation solution. Treatment consists of discontinuation of albuterol sulfate inhalation solution together with appropriate symptomatic therapy. The judicious use of a cardioselective beta-receptor blocker may be considered, bearing in mind that such medication can produce bronchospasm. There is insufficient evidence to determine if dialysis is beneficial for overdosage of albuterol sulfate inhalation solution.
The oral median lethal dose of albuterol sulfate in mice is greater than 2000 mg/kg (approximately 810 times the maximum recommended daily inhalation dose for adults on a mg/m^2 basis or approximately 300 times the maximum recommended daily dose for children on a mg/m^2 basis). In mature rats, the subcutaneous (sc) median lethal dose of albuterol sulfate is approximately 450 mg/kg (approximately 365 times the maximum recommended daily inhalation dose for adults on a mg/m^2 basis or approximately 135 times the maximum recommended daily inhalation dose for children on a mg/m^2 basis). In small young rats, the sc median lethal dose is approximately 2000 mg/kg (approximately 1600 times the maximum recommended daily inhalation dose for adults on a mg/m^2 basis or approximately 600 times the maximum recommended daily inhalation dose for children on a mg/m^2 basis). The inhalational median lethal dose has not been determined in animals.

DOSAGE AND ADMINISTRATION
To avoid microbial contamination, proper aseptic techniques should be used each time the bottle is opened. Precautions should be taken to prevent contact of the dropper tip of the bottle with any surface, including the nebulizer reservoir and associated ventilatory equipment. In addition, if the solution changes color or becomes cloudy, it should not be used.
Children 2 to 12 Years of Age: For children 2 to 12 years of age, initial dosing should be based upon body weight (0.1 to 0.15 mg/kg per dose), with subsequent dosing titrated to achieve the desired clinical response. Dosing should not exceed 2.5 mg three to four times daily by nebulization. The following table outlines approximate dosing according to body weight.

Approximate Weight (kg)	Approximate Weight (lb)	Dose (mg)	Volume of Inhalation Solution
10-15	22-33	1.25	0.25 mL
>15	>33	2.5	0.5 mL

The appropriate volume of the 0.5% inhalation solution should be diluted in sterile normal saline solution to a total volume of 3 mL prior to administration via nebulization.
Adults and Children Over 12 Years of Age: The usual dosage for adults and children 12 years of age and older is 2.5 mg of albuterol administered three to four times daily by nebulization.
More frequent administration or higher doses are not recommended. To administer 2.5 mg of albuterol, dilute 0.5 mL of the 0.5% inhalation solution with 2.5 mL of sterile normal saline solution. The flow rate is regulated to suit the particular nebulizer so that albuterol sulfate inhalation solution will be delivered over approximately 5 to 15 minutes.
The use of albuterol sulfate inhalation solution can be continued as medically indicated to control recurring bouts of bronchospasm. During this time most patients gain optimal benefit from regular use of the inhalation solution.
If a previously effective dosage regimen fails to provide the usual relief, medical advice should be sought immediately as this is often a sign of seriously worsening asthma that would require reassessment of therapy.
Drug compatibility (physical and chemical), efficacy, and safety of albuterol sulfate inhalation solution when mixed with other drugs in a nebulizer have not been established.

HOW SUPPLIED
Albuterol sulfate inhalation solution, 0.5% is supplied in amber glass bottles, with a calibrated dropper and with patient instructions in the following size:
20 mL bottles (NDC 59930-1647-2).

STORAGE
Store between 2°-25°C (36°-77°F).
KEEP OUT OF REACH OF CHILDREN.
*Potency expressed as albuterol
Rx only
FOR ORAL INHALATION ONLY

MANUFACTURER INFORMATION
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Tampa, FL 33637
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Revised May 2008
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PHARMACIST — DETACH HERE AND GIVE INSTRUCTIONS TO PATIENT

PATIENT INSTRUCTIONS FOR USE
Albuterol Sulfate Inhalation Solution, 0.5%*
*Potency expressed as albuterol
Read complete instructions carefully beforeusing.
1. Draw the appropriate volume of albuterol sulfate inhalation solution, 0.5% into the specially marked dropper that comes with each multidose bottle. For children 12 years of age and under, the volume is based upon body weight. Use the dropper volume prescribed by your doctor.

2. Squeeze the solution into the nebulizer reservoir through the appropriate opening, taking care not to touch the tip of the dropper.

3. Add sterile normal saline solution, as your doctor has directed. A general guideline for the amount of saline to add is: For children using 0.25 mL or 1.25 mg of albuterol sulfate inhalation solution, add 2.75 mL of sterile normal saline. For children or adults using 0.5mL or 2.5mg of albuterol sulfate inhalation solution, add 2.5 mL of sterile normal saline.
4. Gently swirl the nebulizer to mix the contents and connect it with the mouthpiece or face mask.
5. Connect the nebulizer to the compressor.

6. Sit in a comfortable, upright position; place the mouthpiece in your mouth (or put on the face mask); and turn on the compressor.

7. Breathe as calmly, deeply, and evenly as possible until no more mist is formed in the nebulizer chamber (about 5 to 15 minutes). At this point, the treatment is finished.
8. Clean the nebulizer (see manufacturer's instructions).
Note: Use only as directed by your physician.More frequent administration or higherdoses are not recommended.
To avoid microbial contamination, proper aseptic techniques should be used each time the bottle is opened. Precautions should be taken to prevent contact of the dropper tip of the bottle with any surface, including the nebulizer reservoir and associated ventilatory equipment. In addition, if the solution changes color or becomes cloudy, it should not be used. The safety and effectiveness of albuterol sulfate inhalation solution have not been determined when one or more drugs are mixed with it in a nebulizer. Check with your doctor beforemixing anymedications in your nebulizer.
Storage: Store between 2°-25°C (36°- 77° F).
ADDITIONAL INSTRUCTIONS:

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